SILMET

K101869

SEP 29 2010

5. 510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of 21 C.F.R. part 872.3275

Date prepared: June 29, 2010

Company

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Devices

Trade Name:	**ProGlass Cements** (ProGlass One, ProGlass Two, ProGlass Two LC, ProGlass Nine, ProGlass Plus, ProGlass Silver)
Classification Name:	Cement, Dental (872.3275)
Common Name:	Glass Ionomer Cements
Regulatory class:	Class II

Predicate Devices

Fuji I	(K980695, GC America)
Fuji II	(K980682, GC America)
Fuji II LC	(K961584, GC America)
Fuji IX	(K961448, GC America)
Fuji Duet (Fuji Plus)	(K946100 GC America)
Miracle Mix	(K984505, GC America)

Description

The **ProGlass cements** are classified as a Dental Cement (21 C.F.R. part 872.3275) because they are devices composed of various materials other than zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.

Device function, scientific concept, physical and performance characteristics

Glass Ionomer Cements are based on the reaction of silicate glass powder and polyalkeonic acid (acid – base reation) and have the following essential components:

- an ionic polymer which is a polycarboxylic acid
- water
- a fluoroaluminosilcate (FAS) glass powder
- tartaric acid.

The above components are formulated to provide a powder and a liquid portion. In use the two are combined and a chemical reaction takes place to provide a set cement.

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General Applications

- Luting crowns, bridges and orthodontic brackets
- Restorative cements
- Lining cements, Base.

Table 1: Device characteristics

		Components	
	Function	**Powder**	**Liquid**
ProGlass One	Luting Cement	Alumino-silicate glass Polyacrylic acid	Distilled water Polyacrylic acid
ProGlass Two	Restorative	Alumino-silicate glass Polyacrylic acid	Distilled water Polyacrylic acid
ProGlass Two LC	Reinforced Restorative Base/Liner	Alumino-silicate glass	Distilled water Polyacrylic acid 2-hydroxyethyl methacrylate (HEMA) 2,2,4, Trimethyl hexamethylene dicarbonate (TMHMD)
ProGlass Nine	Restorative Base/Liner	Alumino-silicate glass Polyacrylic acid	Polyacrylic acid Tartaric acid Distilled water
ProGlass Plus	Luting Cement	Alumino-silicate glass	Distilled water Polyacrylic acid 2-Hydroxyethylmethacrylate Urethanedimethacrylate
ProGlass Silver	Restorative	Alumino-silicate glass Silver	Polyacrylic acid

Table 2: Physical characteristics

	ProGlass One	ProGlass Two	ProGlass Two LC	ProGlass Nine	ProGlass Plus	ProGlass Silver
Powder /liquid	2.4 / 1.0	3.5 / 1.0	2.3 /1.0	4.1 / 1.0	1.5 / 1.0	4.0 / 1.0
Mixing time (sec)	30"	30"	30"	30"	30"	20"
Working time	2' 30" – 3"	1' 30" – 2'	3'	2' 30"	3'	1'40"
Setting Time (min.sec)	3'10"-	3' 10" – 3'	3'	3' 30"	3'	4'
Light Cure (sec)			20"			

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Indications for use

Products	Indications for Use
ProGlass One	Cementation of all types of metal, porcelain fused to metal, resin crowns, inlays, onlays & bridges Cementation of orthodontic bands Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns Base/liner
ProGlass Two	Class III, V and limited class I cavities Restoration of primary teeth Core Build Up
ProGlass Two LC	Class III and V restorations Restoration of Cervical erosions and root surface caries Core Build Up Base/Liner
ProGlass Nine	Class I & II cavities Decidious teeth: final restorative for Class I, II and V Long term restorative in non-load bearing areas of Class I, II and V Intermediate restorative & sandwich material for heavy stress bearing Core build up material
ProGlass Plus	Metal-based restorations Ceramic inlays Reinforced ceramic crowns and bridges All kinds of acrylic/resin crowns, inlays, onlays and bridges
ProGlass Silver	Class I, limited Class II, temporary fillings Restoration of primary teeth Core Build Up Base/Liner

Contraindications: Pulp capping

Technological characteristics

All of the components of **ProGlass Cements** are found in the legally marketed devices:

Fuji I (K980695, GC America), Fuji II (K980682, GC America), Fuji II LC (K961584, GC America), Fuji IX (K961448, GC America), Fuji Plus (K946100 , GC Ameriea) , Miracle Mix (K984505, GC America)

The material, design and use concept is similar.

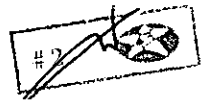
The prior use of all the components in the legally marketed devices supports our decision that additional testing for cytotoxicity and mutagenicity as well as additional bio-compatibility studies with the final formulation are not necessary.

We believe that the prior use of these components in legally marketed devices and the performance data and results support the safety and effectiveness of **ProGlass Cements** for the intended use.

Conclusion

In accordance with 21 C.F.R. part 872.3275 and FDA's " Guidance for the preparation of Premarket Notifications for Dental Cements" and based on the information provided in this premarket notification, Silmet Ltd. concludes that **ProGlass Cements** are safe and effective and substantially equivalent to the predicate devices described herein.

SILMET LTD. 29 June 2010 CEO: Moshe Zalsman Signature:



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Sharon Chaplik
SILMET, Limited
12 Hasadna or Yehuda
Israel 60200

SEP 29 2010

Re: K101869
Trade/Device Name: ProGlass Cements (ProGlass One, ProGlass Two, ProGlass Two LC, ProGlass Nine, ProGlass Plus, ProGlass Silver
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: June 29, 2010
Received: July 2, 2010

Dear Ms. Chaplik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use Statement

SEP 2 9 2010

510(k) Number (if known): K101869

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Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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